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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/530,795	06/25/2000	BRIAN C. KELLER	270142000300 21	4731

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EXAMINER	
HENDRICKS, KEITH D	

ART UNIT	PAPER NUMBER
1761	

DATE MAILED: 09/05/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)
	09/530,795	KELLER ET AL.
	Examiner	Art Unit
	Keith Hendricks	1761

-- The MAILING DATE f this communication app ars on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *17 July 2003* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *15-23* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *15-23* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *20* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on July 17, 2003 has been entered.

Claim Rejections - 35 USC § 112

i) The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 15-23 remain rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

As previously stated on the record, the range of "0.2% to 2%" does not find support for the selection of these particular endpoints from the disclosed ranges.

Applicant's arguments filed July 17, 2003 have been fully considered but they are not persuasive. At pages 5-6 of the response, applicant attempts to provide support for the claimed range. However, applicant's arguments refer to the total of a "Formula", whereas the *claimed ranges* state "between 0.2% to 2.0% (w/w) of *the total liposome composition*" (emphasis added). Applicant's arguments are not commensurate in scope with the claimed invention. See also the rejection under 35 U.S.C. 112, second paragraph, below, where it is again confusing as to the metes and bounds of the "liposomal-based preparation" and an "infant formula."

Again, the range of "0.2% to 2%", with regard to the phospholipid content, is improper, even with respect to the passing reference at page 2 of the specification, which states that "phospholipids and cholesterol contribute 1-2% of total fat" to human milk. This does not equate to, nor support, the range of phospholipids (alone) in concentrations of "0.2% to 2%".

Applicant has provided no guidance, support or explanation as to the (improper) addition of these ranges. Deletion of the rejected new subject matter is required.

ii) The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 15-23 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

It remains unclear as to how the simple two-component liposome, or "liposomal-based preparation" may itself be "useful as an infant formula." The specification discloses the use of such liposomes *within infant formulas*, along with other infant formula components. The claims are confusing because, for example, while claim 15 provides preparations "*comprising* a natural bilayer-forming lipid component and an active ingredient component", it later refers to the lipid component as being a percentage of the "total liposome composition". However, it does not provide prior antecedent basis for the "total liposome composition, and does not provide other lipid or liposomal components such that a "total" may be calculated.

It is noted that applicants' use of phrases such as "liposomal-based preparation", "lipid component", "total lipid composition" (all claim 15), and "liposome preparation" (claims 16-23) do not serve to clarify the invention. The metes and bounds of each of these phrases is unclear, both individually and with regard to how they may overlap and relate to one another.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 15-23 remain rejected under 35 U.S.C. 102(e) as being anticipated by Mehansho et al.

Applicant's arguments filed July 17, 2003, have been fully considered but they are not persuasive. At pages 7-8 of the response, applicant states that "the currently claimed preparations are comprised of between 0.2% to 2% (w/w) phospholipids." This is not deemed persuasive for the reasons of record, and does not appear to be an accurate account of the *claimed* invention. The claimed preparations *comprise* "a natural bilayer-forming lipid component and an active ingredient component". The claims are confusing because, for example, claim 15 later refers to the lipid component as being a percentage of the "total liposome composition"; however, it does not provide prior antecedent basis for the "total liposome composition, and does not provide other lipid or liposomal components such that a "total" may be calculated. Thus, the claimed invention cannot be properly compared against the prior art in the manner in which applicants assert. The Examiner has determined the scope and contents of the prior art, as well as that of the *claimed* invention, to the best that the claims allow, and has properly applied the art of record.

Applicant's comment at the fourth full paragraph of page 7 of the response, regarding "the preparation of the presently claimed liposomal-based infant formulas", is inaccurate and a misleading representation of the claimed invention. Again, the claimed invention is not directed to infant formulas. The claims, at best, state that the claimed invention is "useful as an infant formula". This is, at best, a statement of intended use of the claimed invention. A recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. In a claim drawn to a process of making, the intended use must result in a manipulative difference as compared to the prior art. See *In re Casey*, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963).

In fact, applicant's previous response of April 04, 2002, attempted to state that "the present claims are limited to liposomal-based infant formula preparations." This was, of course, not deemed persuasive, as the claims simply state that the preparations are "useful as an infant formula", and are not limited to an "infant formula", *per se*. Further, as stated at that juncture, it remains unclear as to why the chocolate milk formulation of Mehansho would not serve this purpose.

Applicant has again stated, now at page 8, that "Mehansho does not disclose preparations which would closely resemble the composition of human milk or the claimed compositions," and which would be useful as an infant formula. However, no rationale or support for this statement is provided. The phospholipid concentration is addressed at columns 6-7 of the reference, where it is stated that the edible carrier may be a liposome, and may serve to carry a divalent mineral salt, where "the ratio of divalent mineral salt to edible carrier can vary widely, but is typically in the range of from about 1:1 to about 1:500." This reads upon the lipid component (i.e. that which is the liposome. See applicants' own specification, pg. 3) in a concentration of "50%". Note that applicant's currently-claimed range of "0.2-2%" is subject to a new matter rejection under 35 USC 112, 1st paragraph, and thus the ultimate scope of the claimed invention is presently in question. At this time, the rejection will stand for the reasons of record.

Regardless, it is noted that lecithin (phospholipid) in the chocolate powder mix of Example 1 of the reference is used in an amount of 0.3 percent, thus reading on the instantly-claimed invention. Column 4, lines 34-37 of the reference specifically states that "chocolate-flavored edible mixes according to the present invention *can be used in the preparation* of various chocolate-flavored products, including cereal products, *baby foods or formulas*," etc. Note that applicant's disclosure and even original claims 13-14 allotted for powder preparations useful for baby formulas.

Again, absent any clear and convincing evidence and/or arguments to the contrary, if the same standard liposome structure is provided, as well as the same micronutrient components within, then it must be presumed and expected that the reference provides a composition of the two having a size within the instantly-claimed range.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Keith Hendricks whose telephone number is (703) 308-2959.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Milton Cano, can be reached at (703) 308-3959. The fax phone number for the organization where this application or proceeding is assigned is (703) 305-3602.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0661.

KEITH HENDRICKS
PRIMARY EXAMINER